PCT/GB2005/000494.

INVESTOR IN PEOPLE

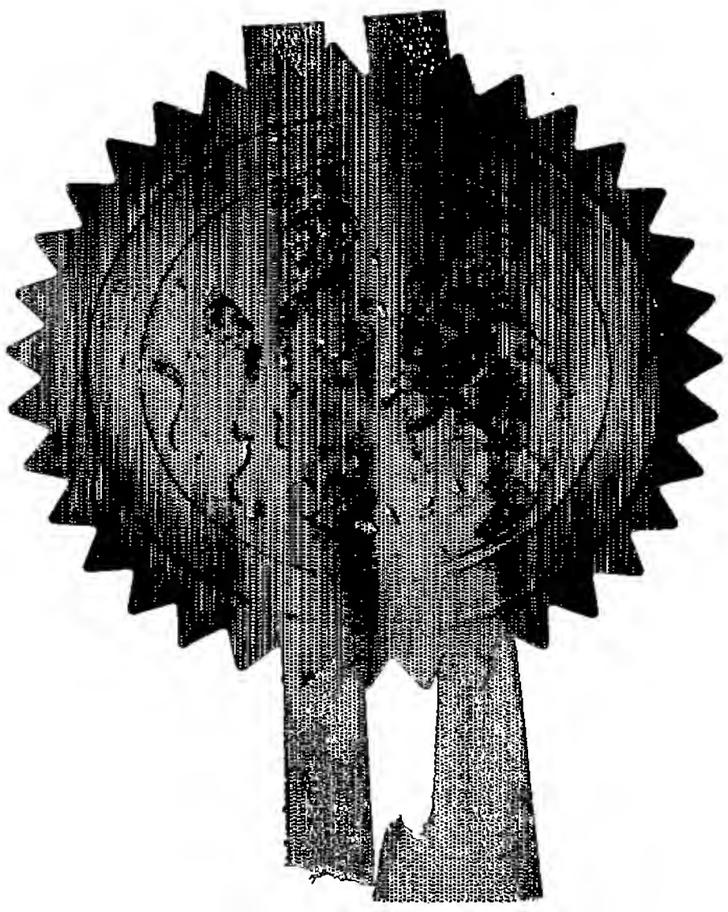
The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.



Signed William Morell

Dated 22 March 2005

Patents Form 1/77

Patents Act 1977
(Rule 16)

THE PATENT OFFICE
A
11 FEB 2004
NEWPORT

The Patent Office

11FEB04 E872266-1 002866
P01/7700 0.00-0402930.2 CHEQUE

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

1. Your reference — MEDU / P28646GB

2. Patent application number *(The Patent Office will fill in this part)* — 0402930.2 — 11 FEB

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Mediplus Limited
37-39 Baker Street
High Wycombe
Buckinghamshire HP11 2RX
United Kingdom

Patents ADP number *(if you know it)* 7189210001

If the applicant is a corporate body, give the country/state of its incorporation — United Kingdom

4. Title of the invention — CATHETER GUIDE WIRE

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

ERIC POTTER CLARKSON
PARK VIEW HOUSE
58 THE ROPEWALK
NOTTINGHAM
NG1 5DD

Patents ADP number *(if you know it)* **1305010**

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) *any applicant named in part 3 is not an inventor; or*
b) *there is an inventor who is not named as an applicant, or*
c) *any named applicant is a corporate body.*
See note (d))

YES

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	11
Claims*(s)*	5
Abstract	1
Drawing*(s)*	3 + 3

10. If you are also filing in any of the following, state how many against each item.

Priority Documents	0
Translations of priority documents	0
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	YES
Request for preliminary examination and search *(Patents Form 9/77)*	YES
Request for substantive examination *(Patents Form 10/77)*	NO
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature Eric Potter Clarkson

ERIC POTTER CLARKSON

Date 10 February 2004

12. Name and daytime telephone number of person to contact in the United Kingdom

0115 9552211

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 01645 500505.
b) Write your answers in capital letters using black ink or you may type them.
c) If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.
d) If you have answered 'Yes' Patents Form 7/77 will need to be filed.
e) Once you have filled in the form you must remember to sign and date it.
f) For details of the fee and ways to pay please contact the Patent Office.

CATHETER GUIDE WIRE

The present invention relates to guide wires for the insertion of catheters into the human or animal body and in particular, though not exclusively, to guide wires suitable for the insertion of the catheter into the bladder.

Insertion of a flexible catheter into the human bladder via the supra-pubic region can present particular problems. In one conventional technique, a large bore needle having an internal diameter capable of receiving the flexible catheter is used to penetrate the skin, underlying tissue and bladder. A flexible catheter is then introduced into the needle and inserted into the bladder, following which the needle may be withdrawn. This requires the use of a needle having large diameter sufficient to accommodate a catheter and of sufficient strength to penetrate the relative tough supra-pubic tissue area. This requires the use of a needle having an outside diameter that is significantly larger than the outside diameter of the flexible catheter (which itself is typically approximately 4 or 5 mm), thereby forming a hole in the tissue significantly larger than strictly necessary. Great care has to be exercised by the clinician introducing the needle to avoid over- or under-penetration of the needle.

In another conventional technique, a trocar having a stiff penetrative tip (e.g. of medical grade stainless steel) and a stiff outer plastic sheath is inserted into the bladder through the supra-pubic region. The trocar is then withdrawn through the sheath, leaving the sheath in situ, penetrating the bladder through the supra-pubic region. A flexible catheter is then introduced into the bladder through the sheath. The plastic sheath is of the peelable variety, so that once the flexible catheter is introduced into the bladder, the sheath can be split along its entire length, stripped away from the flexible catheter and removed from the body. This leaves the flexible

catheter in situ. A potential drawback with this technique is that the initial penetration of the supra-pubic region is, like the previously described technique, performed with a penetrative instrument having an outside diameter of similar dimensions to the flexible catheter that is eventually introduced (e.g. of the order of 5 mm or so). Therefore, again, the clinician must exercise great care to avoid over-penetration of the bladder and potential damage to the opposite bladder wall.

The present invention seeks to provide an improved method and apparatus for insertion of a flexible catheter into a human or animal body. In one aspect, the invention seeks to provide a guidewire technique to overcome some or all of the disadvantages associated with the prior art.

According to one aspect, the present invention provides a guidewire for introduction into a body via a hollow needle, comprising:

a proximal end having a stiffness greater than 10 N; and

a distal end having a stiffness less than 3 N,

the stiffness being defined as the force required to produce an angular lateral displacement of 30 degrees when applied at a distance of 10 mm along the respective length of guidewire.

According to another aspect, the present invention provides a guidewire for introduction into a body via a hollow needle, comprising:

a proximal end having a first stiffness;

a distal end having a second stiffness less than said first stiffness; and

an intermediate portion having a stiffness lying between the first and second stiffness values.

According to another aspect, the present invention provides a method for introducing a catheter into the bladder of the human body in the supra-pubic region comprising the steps of:

introducing a needle into the bladder via the supra-pubic region, the needle having an outside diameter less than 2 mm;

inserting a guidewire having an outside diameter less than 2 mm into the bladder through an internal bore of the needle;

withdrawing the needle over the guidewire;

introducing a peelable catheter sheath into the bladder over the guidewire, the catheter sheath having a distal end of outside diameter less than approximately 2 mm and a proximal end having an outside diameter of at least 4 mm;

withdrawing the guidewire through the catheter sheath;

inserting a flexible catheter into the bladder through the catheter sheath; and

peeling away the catheter sheath from the flexible catheter leaving the flexible catheter in situ.

According to another aspect, the present invention provides a bladder drainage kit comprising:

a guidewire having an outside diameter less than 2 mm and having a proximal end having a first stiffness and a distal end having a second stiffness, the second stiffness being less than the first stiffness;

a peelable catheter sheath adapted to receive the guidewire and to penetrate the supra-pubic region of the human body using the proximal portion of the guidewire as a guide, the catheter sheath having an inside diameter at its distal end approximately equal to the outside diameter of the guidewire, and an inside diameter at its proximal end of at least 4 mm for receiving a flexible drainage catheter.

Embodiments of the present invention will now be described by way of example and with reference to the accompanying drawings in which:

Figure 1 shows an axial cross-section of a guidewire according to a preferred embodiment of the present invention;

Figure 2 shows an axial cross-section of a centre wire of the guidewire of figure 1;

Figure 3 shows a side view of the complete guidewire of figure 1; and

Figure 4 shows a schematic diagram illustrating a needle, a plastic catheter sheath with peelable outer skin and catheter, useful in explaining a method of use of the guidewire of the present invention.

A feature of the method of the present invention is that a guide wire can be used to significantly reduce the diameter of needle or trocar required to penetrate the bladder. This is particularly significant in the supra-pubic region where the tissue is particularly tough. In the preferred technique, a small diameter needle (e.g. of the order of 1 mm outside diameter) is inserted into the bladder in the supra-pubic region. The relatively small diameter needle is much easier to control during penetration of the tissue.

A thin guidewire is then introduced into the bladder via the needle, such that it extends into the bladder. The needle is then withdrawn over the guidewire, leaving the guidewire in place. A stiff plastic sheath having a distal end which tapers down to a diameter similar to that of the guidewire is introduced into the bladder through the skin and tissue using the guidewire as a guide. This expands the existing hole in the tissue. A flexible catheter is then introduced into the plastic sheath and thereby into the bladder. The plastic sheath is of the peelable variety, so that once the flexible catheter is introduced into the bladder, the sheath can be split along its entire length, stripped away from the flexible catheter and removed from the body. This leaves the flexible catheter in situ. A significant advantage of this procedure

is that the initial penetration of the supra-pubic region is by way of small diameter needle; the expansion of the initial hole can then be performed under the control of a guidewire.

In order to successfully perform this procedure, the guidewire must have a high degree of stiffness in order to facilitate and guide the penetration, into the body, of the relatively larger plastic sheath. Otherwise the pressure being applied on the plastic sheath to displace tough tissue will distort the guidewire. This high stiffness in turn again increases the likelihood of internal damage to the bladder caused by over-insertion of the guidewire, such that the distal end thereof collides with an opposite internal wall of the bladder. Therefore, the clinician must exercise great care not to over-insert the guidewire, despite significant variations in physique of different patients (e.g. the depth and stiffness or muscle tone of tissue to be penetrated).

With reference to figure 1 there is shown a guidewire 1 of a preferred embodiment. The guidewire comprises outer tubing 2, preferably formed from stainless steel, which is filled with a solid core 3, also preferably formed from stainless steel. The outer tubing 2 extends from a proximal end 5 of the guidewire 1 to a first intermediate position 6 where it is welded, brazed or otherwise fixed or bonded to a tightly wound coil 4 of substantially the same outside diameter as the outer tubing 2. The coil 4 extends from the first intermediate position 6 to a distal end 9 of the guidewire 1.

The solid core 3 extends throughout the outer tubing 2 and extends beyond the first intermediate position to the distal end 9 of the guidewire. At the first intermediate position 6, or slightly beyond it at a second intermediate position 7 towards the distal end 9, the solid core 3 commences a taper. The taper ends at a third intermediate position 8. The solid core 8 terminates at

the distal end in a 'mushroom' configuration where it is welded, brazed or otherwise fixed or bonded to the tightly wound coil 4.

As is particularly illustrated in figure 1, the guidewire 1 therefore provides three distinct portions. These are: a first ('proximal') portion 11 extending from the proximal end 5 to the first intermediate position 6; a second ('intermediate') portion 12 extending from the first intermediate position 6 to the third intermediate position 8; and a third ('distal') portion 13 extending from the third intermediate position 8 to the distal end 9.

The combination of the outer tubing 2, the coil 4 and the solid core 3 effectively provides a guidewire 1 having a first stiffness at the proximal end (and generally extending throughout the proximal portion 11 to the first intermediate position 6), a second stiffness at the distal end 9 (and generally extending throughout the distal portion 13 to the third intermediate position 8) in which the second stiffness value is significantly less than the first stiffness value. In the intermediate portion 12, the stiffness value lies between that of the first and second stiffness values and may generally vary over the length thereof.

In the following preferred values, the stiffness is defined as the force required to produce an angular lateral displacement of 30 degrees when applied at a distance of 10 mm along the respective length of guidewire. Preferably, the stiffness of the proximal portion 11 is in excess of 10 N, and more preferably lies within the range 15 to 20 N. Preferably, the stiffness of the distal portion 13 is less than 3 N, and more preferably lies within the range 0.2 to 1 N. Preferably, the stiffness of the intermediate portion 12 lies in the range between that of the adjacent proximal and distal portions, and preferably it has a gradual or stepped reduction in stiffness over the length of

the intermediate portion 12. In preferred embodiments, the stiffness of the intermediate portion lies in the range 5 N to 8 N.

In the preferred arrangement as shown, the outer tubing has an outside diameter approximately 0.0355 inch or 0.0360 inch (900 or 915 microns). The outer tubing has a length of 30 cm. The coil has an outside diameter of approximately 0.0370 inch (940 microns) and a coiled length of approximately 12.5 cm. The solid core 3 has a maximum outside diameter (in the proximal portion) of approximately 0.020 inch (500 microns) and an overall length of approximately 42 cm. The solid core 3 has a diameter tapering to approximately 0.006 inch (150 microns) at the third intermediate position 8 and a length of distal portion of approximately 21 mm. The solid core 3 may taper in the distal portion 13 down to a diameter of between approximately 0.0023 inch and 0.0033 inch (58 to 84 microns).

In another arrangement, the outer tubing and coil have an outside diameter of approximately 750 microns. In a general aspect, the guidewire has an outside diameter of less than 2 mm and preferably less than or equal to 1 mm, e.g. in the range 750 to 1000 microns.

It will be understood that these dimensions may need to be varied in order to provide utility in different regions of the body and possibly for different patient morphology.

More generally, the guidewire 1 preferably has a distal end which extends over a length of between 10 and 15 cm, and more preferably over a length of 12.5 cm ± 1 cm. Preferably, the distal end comprises the distal portion 13 and the intermediate portion 12. In another general arrangement, the guidewire 1 has a distal portion that extends over a length of between 2 and 8 cm and an intermediate portion that extends over a length of between 2

and 8 cm. More preferably, the distal end extends over a length of at least 2 cm and the intermediate portion extends over a length of 4 cm ± 1cm.

The materials used are preferably 304 stainless steel throughout although other clinical grade materials may be considered.

Preferably, the guidewire is provided with reference markings at predetermined positions along its length. With reference to figure 3, the guidewire 1 preferably includes a first reference mark 30 at a distance of 340 mm from the distal end 5 and a second reference mark 31 at a distance of 215 mm from the distal end. The function of the reference marks will become apparent from the description hereinafter.

With reference to figure 4, in a preferred arrangement, the guidewire is deployed in the following manner.

A needle 40 of gauge 1 mm and length 7 mm is introduced into the bladder 41 through the supra-pubic tissue 42. The guidewire 1 is introduced into the bladder 41 through the needle. An important feature of the guidewire is that the distal portion 13 is relatively flexible with minimal stiffness (sufficient to allow convenient introduction into and through the needle) and is unable to cause damage to the internal walls of the bladder 41, especially at a location 43 opposite to the point of entry of the needle 40. Preferably, the intermediate portion 12 has a sufficient increase in stiffness over the distal portion 13 to provide tactile feedback to the clinician. In other words, when the guidewire has been passed into the bladder to an extent that the intermediate portion 12 reaches the opposite bladder wall 43, its collision with the wall will be evident to the clinician by simple change in resistance to further motion.

Despite the increased stiffness of the guidewire at that point, where the intermediate portion reaches the bladder wall 43, the existence of the more flexible (and now curved) distal portion 13 prevents damage to the bladder walls.

At this point, the clinician ceases further entry of the guidewire, and withdraws the needle 40 over the proximal end 11 of the guidewire 1 still outside the body. Following removal of the needle, a stiff plastic sheath, or preferably a pair of coaxial sheaths 44, 45, are slid over the guidewire 1 from its proximal end, preferably up to the point where the first or second reference mark appears (depending upon the type of sheath being used). The stiff plastic sheaths 44 and 45 have a tapered end 46 adapted to form a snug sliding fit over the guidewire 1, ie. having an inside diameter slightly larger than that of the outer tube 2 and coil 4.

The stiff plastic sheath provides a gradual increase in diameter increasing from approximately 1.2 mm outside diameter at its distal end 46 to 6 mm outside diameter for the main body portion 47. In the preferred embodiment, the outer sheath 44 of the coaxial pair of sheaths is formed from a relative thin and frangible plastics material and includes two lugs 48 at the proximal end. The inner sheath 45 is rather more robust and provides the mechanical strength required.

In use, the plastic sheaths are adapted to be guided by the guidewire into the tissue to expand the hole already formed by the needle. Particularly in the supra-pubic region, entry of the plastic sheath encounters significant resistance, increasing the dimension of hole in the tissue from the needle diameter (e.g. 1 mm to 6 mm). An important feature of the guidewire described herein is to provide a stiff proximal portion of the guidewire that is adequate to provide the guiding function, while providing a sufficiently

flexible distal portion to avoid damage to internal walls of the bladder. It has been found that guidewires that are sufficiently flexible to avoid risk of damage to internal walls of the bladder are generally insufficiently stiff to provide adequate guidance to the plastic sheath insertion through certain tissue types in specific regions of the body, e.g. the supra-pubic region.

Once the plastic sheaths 44, 45 have been inserted, the guidewire 1 can be withdrawn. The inner sheath 45 can also be withdrawn. At that time, the desired bladder drainage catheter 50 formed from soft, flexible plastic tubing (e.g. of approximately 4 mm outside diameter) can be introduced into the bladder via the outer stiff plastic sheath 44. Once this action is completed, the stiff plastic sheath 44 can be removed by tearing along its length. In other words, the clinician may grasp the lugs 48 and strip or peel the plastic sheath 44 away, withdrawing the distal portion contained within the body while doing so.

In a general aspect, the plastic sheath 44 has a distal end of inside diameter approximately equal to the outside diameter of the guidewire, and a proximal end of inside diameter sufficient to receive the flexible catheter, e.g. at least 4 mm.

The use of a guidewire having at least two grades of stiffness, and preferably at least three, along its length, facilitates the provision of several important features. Firstly, the guidewire can be sufficiently stiff or rigid in the proximal portion to ensure adequate guidance of the sheath which expands the needle hole. At the same time, the flexible distal end protects the bladder internal walls from damage.

Secondly, the graduated stiffness in the intermediate portion provides the clinician with tactile feedback of the positioning of the guidewire within the bladder.

It will be understood that the stiffness of the various distal, intermediate and proximal portions need not be invariant along the length of the respective portion.

It will be understood that, throughout the present description, the dimensions of the various components of the preferred embodiments are illustrative only.

Other embodiments are intentionally within the scope of the accompanying claims.

CLAIMS

1. A guidewire for introduction into a body via a hollow needle, comprising:

a proximal end having a stiffness greater than 10 N; and

a distal end having a stiffness less than 3 N,

the stiffness being defined as the force required to produce an angular lateral displacement of 30 degrees when applied at a distance of 10 mm along the respective length of guidewire..

2. The guidewire of claim 1 further including an intermediate portion having a stiffness lying between the stiffness of the proximal end and the distal end.

3. The guidewire of claim 1 in which the distal end comprises a coil having a central core.

4. The guidewire of claim 2 in which the distal end and the intermediate portion comprise a coil having a central core, the core having a first diameter in the intermediate portion greater than a second diameter in the distal portion.

5. The guidewire of claim 4 in which the central core has a tapering diameter in the intermediate portion towards the distal end.

6. The guidewire of claim 1 in which the distal end extends over a length of between 10 and 15 cm.

7. The guidewire of claim 6 in which the distal end extends over a length of 12.5 cm ± 1 cm.

8. The guidewire of claim 2 in which the distal end extends over a length of between 2 and 8 cm, and in which the intermediate portion extends over a length of between 2 and 8 cm.

9. The guidewire of claim 8 in which the distal end extends over a length of at least 2 cm and in which the intermediate portion extends over a length of 4 cm ± 1 cm.

10. The guidewire of any one of claims 1 to 9 in which the proximal end comprises a hollow tube containing a wire core.

11. A guidewire for introduction into a body via a hollow needle, comprising:

a proximal end having a first stiffness;

a distal end having a second stiffness less than said first stiffness; and

an intermediate portion having a stiffness lying between the first and second stiffness values.

12. The guidewire of claim 11 in which the distal end comprises a coil having a central core.

13. The guidewire of claim 12 in which the distal end and the intermediate portion comprise a coil having a central core, the core having a first diameter in the intermediate portion greater than a second diameter in the distal portion.

14. The guidewire of claim 13 in which the central core has a tapering diameter in the intermediate portion towards the distal end.

15. The guidewire of claim 11 in which the distal end extends over a length of between 10 and 15 cm.

16. The guidewire of claim 15 in which the distal end extends over a length of 12.5 cm ± 1 cm.

17. The guidewire of claim 11 in which the distal end extends over a length of between 2 and 8 cm, and in which the intermediate portion extends over a length of between 2 and 8 cm.

18. The guidewire of claim 7 in which the distal end extends over a length of at least 2 cm and in which the intermediate portion extends over a length of 4 cm ± 1 cm.

19. The guidewire of any one of claims 11 to 18 in which the proximal end comprises a hollow tube containing a wire core.

20. The guidewire of any preceding claim in which the proximal end has a stiffness adapted to facilitate the guiding of a substantially rigid catheter sheath of diameter in the range 5 to 7 mm into the bladder via the supra-pubic region of the human body.

21. The guidewire of any preceding claim forming part of a kit comprising: a hollow needle having an inside diameter adapted for receiving the guidewire; and a catheter sheath having an internal diameter adapted to receive the guidewire and to penetrate the supra-pubic region of the human body using the proximal portion of the guidewire as a guide, the catheter sheath having a peelable outer skin.

22. A bladder drainage kit comprising:

a guidewire having an outside diameter less than 2 mm and having a proximal end having a first stiffness and a distal end having a second stiffness, the second stiffness being less than the first stiffness;

a peelable catheter sheath adapted to receive the guidewire and to penetrate the supra-pubic region of the human body using the proximal portion of the guidewire as a guide, the catheter sheath having an inside diameter at its distal end approximately equal to the outside diameter of the guidewire, and an inside diameter at its proximal end of at least 4 mm for receiving a flexible drainage catheter.

23. The kit of claim 22 in which the peelable catheter sheath further includes an inner sheath for stiffening the peelable catheter sheath during insertion into the body, the inner sheath being withdrawable from the proximal end of the peelable catheter sheath.

24. The kit of claim 22 or claim 23 in which the guidewire has a diameter at its distal end in the range 750 to 1000 microns.

25. A method for introducing a catheter into the bladder of the human body in the supra-pubic region comprising the steps of:

introducing a needle into the bladder via the supra-pubic region, the needle having an outside diameter less than 2 mm;

inserting a guidewire having an outside diameter less than 2 mm into the bladder through an internal bore of the needle;

withdrawing the needle over the guidewire;

introducing a peelable catheter sheath into the bladder over the guidewire, the catheter sheath having a distal end of outside diameter less than approximately 2 mm and a proximal end having an outside diameter of at least 4 mm;

withdrawing the guidewire through the catheter sheath;

inserting a flexible catheter into the bladder through the catheter sheath; and

peeling away the catheter sheath from the flexible catheter leaving the flexible catheter in situ.

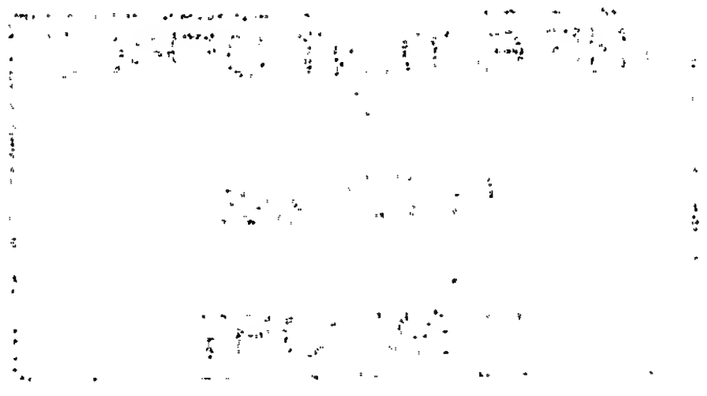
26. Apparatus substantially as described herein and with reference to the accompanying drawings.

ABSTRACT

CATHETER GUIDE WIRE

A catheter guidewire for facilitating introduction of a flexible catheter into the human body (e.g., into the bladder) has a proximal end having a first stiffness which is sufficient to facilitate guidance of a stiff plastic expansion sheath through the tissue. A distal end of the guide wire has a second stiffness, substantially less than the first stiffness, to avoid damage to internal walls of the bladder. Preferably, the guide wire incorporates an intermediate portion having a stiffness between the first stiffness value and the second stiffness value.

Figure 1



Device Configuration	Tubing P/N	Tubing OD	Hypotube Length	Coil Dimensions	Core Dimensions	Overall Length
LSFU 038-42	K 20 R	0.0355" - 0.0360"	30cm ± 2mm	0.0370" x 12.5cm (0.007")	0.020" x 43cm	42cm ± 5mm

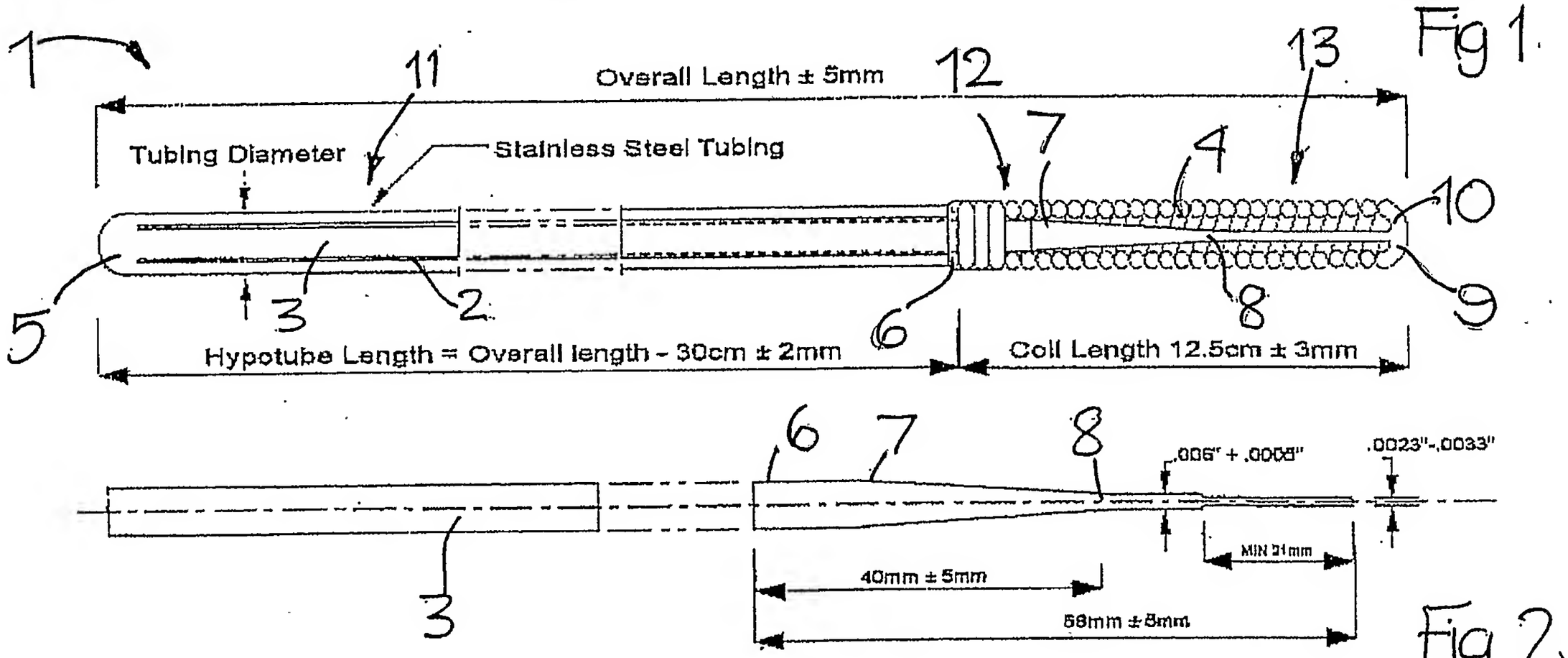


Fig 1

Fig 2

Device Attributes

Dimensional: As detailed in above table.

Tensile: As per ISO 11070:1999: Annex H

Tactile: Devices smooth to touch, free from any bumps, burrs, splits on other surface imperfections.

Cleanliness: Devices free from any surface soils / contaminents

Material Details: Chemical Composition (Percent) - Typical representation
Subject to tolerance and check analysis given per specification submitted

Material Type : 304 Stainless Steel															
	C	Mn	P	S	Si	Cr	Ni	Mo	Fe	Ti	Al	N	Cu	Co	Se
Spring Wire	.072	1.26	.017	.001	.72	18.62	8.74	.10	-	-	-	.038	.06	.03	-
Core Wire	.078	1.28	.018	.003	.68	18.57	8.68	-	-	-	-	-	-	-	-

Biocompatability:

Ref: Std. ISO 10993 : Biological Evaluation of Medical Devices						
Haemolysis	Cytotoxicity	Systemic Toxicity	Intracutaneous Reactivity	Sensitisation	LAL	Bioburden
Pass	Pass	Pass	Pass	Pass	Pass	Pass

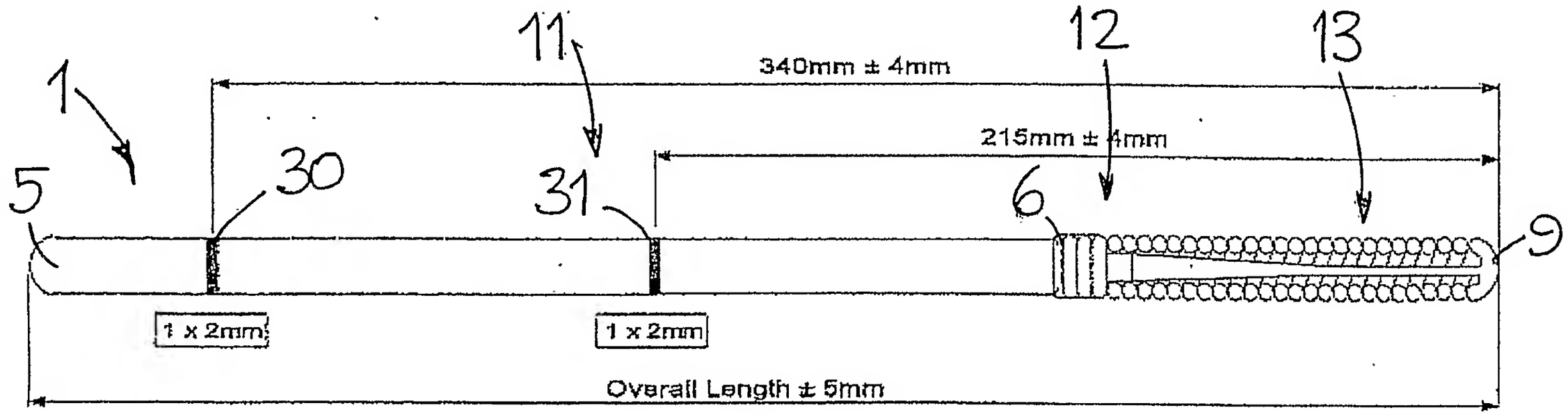
Quality Assurance: TFX Medical - Lurgan operates a Quality Management System certified to the requirements of:

BS EN ISO 9001 : 1994
BS EN ISO 13485 : 2001
BS EN 46001 : 1996

510K: K963320

Device Configuration	Customer Code
LSFU 038-42	TBA

Fig 3



Device Characteristics:

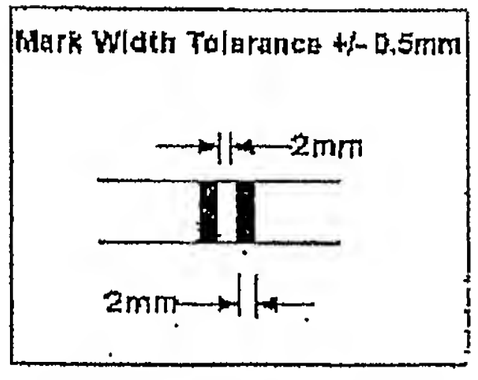
1 Mark width is 2mm ± 0.5mm with a 2mm spacing between consecutive marks unless otherwise specified.

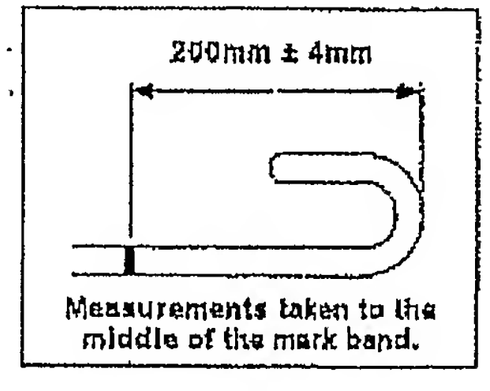
2 Marks should be concentric around the diameter of the guidewire.

3 Mark colour should be dark grey to light black, electrolyte staining is not acceptable.

4. Marking process - electro-chemical etch.

5 Marking definition shall be clear and defined, allowing for accurate depth judgement.





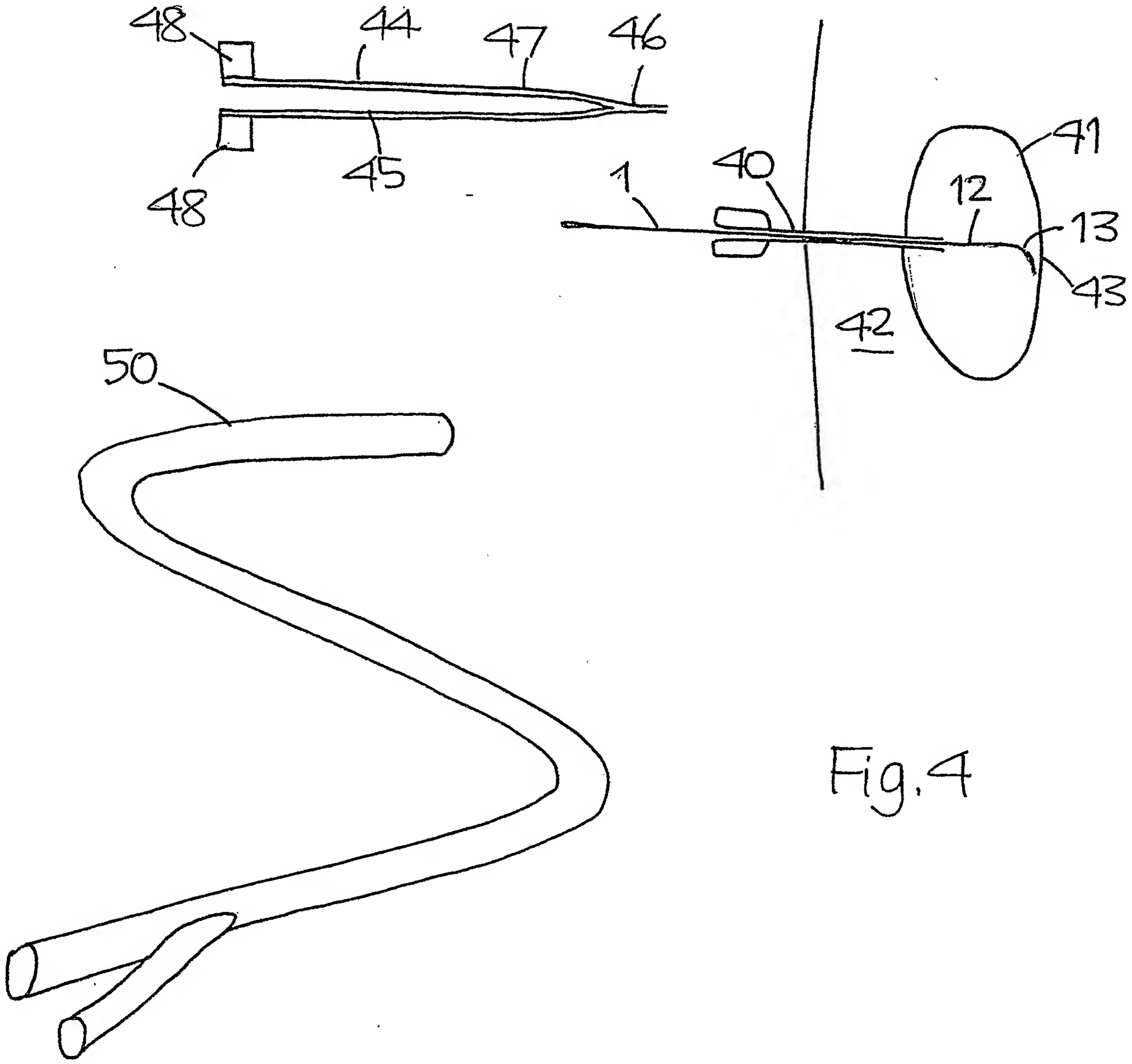


Fig.4